December 13, 2023

Tyto Care Ltd.
Stella Perry
RA&QA Director
14 Beni Gaon Street
Natanya, 4250803
Israel

Re: K232237
Trade/Device Name: Tyto Insights for Wheeze Detection
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic Pulmonary-Function Interpretation Calculator
Regulatory Class: Class II
Product Code: PHZ
Dated: November 13, 2023
Received: November 14, 2023

Dear Stella Perry:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232237

Device Name
Tyto Insights for Wheeze Detection

Indications for Use *(Describe)*
The Tyto Insights for Wheeze Detection is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter Name and Address:	Tyto Care Ltd. 14 Beni Gaon Street Netanya, Israel, 4250803
Contact Person:	Stella Raizelman Perry RA & QA Director Email: stellar@tytocare.com Phone Number: +972 72-2210750 Fax Number: +972 72-2210752
Establishment Registration Number:	3012678246
Date Prepared:	December 13, 2023
Device Trade Name(s):	Tyto Insights for Wheeze Detection
Device Common Name:	Tyto Insights for Wheeze Detection
Classification:	**Name:** Diagnostic pulmonary-function interpretation calculator **Product code:** PHZ **Regulation No:** 21 CFR 868.1900 **Class**: II **Panel:** Anesthesiology

Predicate Device(s):

Device name	510(k) No.	Date of Clearance
TytoCare Lung Sounds Analyzer	K221614	January 26, 2023

Reference Device(s):

Device name	510(k) No.	Date of Clearance
eMurmur Heart AI	K220766	May 31, 2022

Intended use / indication for use statement

The Tyto Insights for Wheeze Detection is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.

Device description

The Tyto Insights for Wheeze Detection is a web-based (AI) enabled software system designed to aid in the clinical assessment of lungs auscultation sound data by analyzing recorded lung sounds to determine whether a Wheeze is detected within the recorded sound data.

The Tyto Insights for Wheeze Detection Software is intended to process recordings from the FDA-cleared compatible Tyto Stethoscope (Tyto Stethoscope, K181612). The acquisition of the acoustic data (recordings) is carried out by a professional user in a clinical environment or by a lay- user in a non-medical environment, in compliance with the labeling of the Tyto Stethoscope. The system is composed of the following sub-systems:

1. The Tyto Insights for Wheeze Detection Application Server (APS) communicates with the Tyto Insights for Wheeze Detection Algorithm Server (ALS) and implements an application programming interface (API) for communication with the telehealth server.
2. The Tyto Insights for Wheeze Detection Algorithm Server (ALS) receives an audio file as input and returns an analysis result of positive or negative regarding whether a wheeze was detected as output.
3. The Tyto Insights for Wheeze Detection Web Server (WBS) provides a graphic indication whether a wheeze is detected in the recording. It can be utilized both in patient and clinician side.

All the software subsystems (servers and storage) are hosted in the cloud and communicate through IP network.

Substantial Equivalence to Predicate Devices

The following table compares the Tyto Insights for Wheeze Detection to the predicate device.

Table 1. Substantial Equivalence Summary

	Device	Predicate device	Reference device	Summary
Device Name	Tyto Insights for Wheeze Detection	TytoCare Lungs Sounds Analyzer	eMurmur Heart AI	NA
Device Manufacturer	Tyto Care Ltd.	Tyto Care Ltd.	CSD Labs GmbH	NA
510(k) Number	K232237	K221614	K220766	NA
Device Class	Class II	Class II	Class II	Same as the predicate device.
Review Panel	Anesthesiology	Anesthesiology	Cardiology	Same as the predicate device.
Product code	PHZ	PHZ	DQD, DQC	Same as the predicate device.
Regulation number	21 CFR 868.1900	21 CFR 868.1900	21 CFR 870.1875	Same as the predicate device.
Classification Name	Diagnostic pulmonary-function interpretation calculator, Stethoscope	Diagnostic pulmonary-function interpretation calculator, Stethoscope	Electronic Stethoscope; Phonocardiograph;	Same as the predicate device.

Intended use and indication for use	The "Tyto Insights for Wheeze Detection" is an over-the-counter artificial intelligence (AI) enabled decision support software system used in the evaluation of lung sounds in adults and pediatrics (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the Tyto Insights for Wheeze Detection result. Healthcare providers should consider the device result in conjunction with recording and other relevant patient data.	The TytoCare Lung Sounds Analyzer is an over-the-counter decision support software system used in the evaluation of lung sounds in adults and children (2 years and older). It automatically analyzes the acoustic signal of the lung as recorded by the FDA cleared compatible Tyto Stethoscope and identifies recordings where a specific abnormal lung sound suggestive of "Wheeze", is suspected. It is not intended to detect other abnormal or normal lung sounds. A licensed health care professional's advice is required to understand the meaning of the TytoCare Lung Sounds Analyzer result. Healthcare providers should consider the device result in	The 'eMurmur Heart AI' software is a decision support system in the evaluation of recorded patient heart sounds. The automated analysis by eMurmur Heart AI identifies specific heart sounds that may be present, including S1, S2, physiological heart murmurs, pathological heart murmurs and the absence of a heart murmur. eMurmur Heart AI is indicated for use in a setting where auscultation would typically be performed by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by eMurmur Heart AI are only significant when considered in conjunction with healthcare provider over-read and including all other relevant patient data.	Same as the predicate device.

	Device	Predicate device	Reference device	Summary
		conjunction with recording and other relevant patient data.		
Type of use	Over-The-Counter Use	Over-The-Counter Use	Prescription use	Same as the predicate device.
Intended users	Intended to be used by professional users and lay users (18-65 years old).	Intended to be used by professional users and lay users (18-65 years old).	Professional users	Same as the predicate device.
Intended patient population	Intended for patients of 2 years and older	Intended for patients of 2 years and older	Intended for patients of all ages	Same as the predicate device.
Intended environment	Non-clinical (home) and clinical	Non-clinical (home) and clinical	Clinical setting	Same as the predicate device
Form	Stand-alone software system	Stand-alone software system	Stand-alone software system	Same
Device composition	The following modules compose the Tyto Insights for Wheeze Detection: • The Tyto Insights for Wheeze Detection Application Server (APS) • The Tyto Insights for Wheeze Detection Algorithm Server (ALS) • The Tyto Insights for Wheeze Detection Web	The following modules compose the TytoCare Lung Sounds Analyzer: • The TytoCare Lung Sounds Analyzer Application Server (APS) • The TytoCare Lung Sounds Analyzer Algorithm Server (ALS) • The TytoCare Lung Sounds Analyzer Web	'eMurmur' is a non-medical device software platform which includes the eMurmur apps and eMurmur web portal. eMurmur Heart AI interacts with the 'eMurmur' software platform.	Same as the predicate device Both the subject device and the reference device include AI enabled algorithm designed for the analysis of stethoscope recordings.

	Device	Predicate device	Reference device	Summary
	Server (WBS) provides a graphic indication whether a wheeze is detected in the recording It can be utilized both in patient and clinician side.	Server (WBS) provides a graphic indication whether a wheeze is detected in the recording It can be utilized both in patient and clinician side.		
Input	Lung sounds recorded by compatible Tyto Stethoscope	Lung sounds recorded by compatible Tyto Stethoscope	Acquires acoustic signals by means of compatible electronic stethoscope	Same
Device technology and operating principle	The recordings are created by the compatible Tyto Stethoscope (K181612) and are sent by the third-party point of care app to the clinician app through the telehealth server. The telehealth server sends the set of the lung sound recordings to the Tyto Insights for Wheeze Detection web server using its dedicated API. The telehealth server subsequently sends the link to results and the relevant UI web view to	The recordings are created by the compatible Tyto Stethoscope (K181612) and are sent by the third-party point of care app to the clinician app through the telehealth server. The telehealth server sends the set of the lung sound recordings to the TytoCare Lung Sounds Analyzer web server using its dedicated API. The telehealth server subsequently sends the link to results and the relevant UI web view to	To analyze heart sounds via the eMurmur Heart AI, a digital recording of a patient's heart sounds is required. Recordings are made using a supported digital stethoscope, connected to a front-end client like, e.g., the eMurmur app or the eMurmur web portal. The recorded auscultation data are transmitted from the front-end client to the eMurmur backend, which hosts the eMurmur Heart AI. After analysis by the eMurmur Heart AI, the results of the analysis are	Similar The proposed device, the predicate and reference device acquire lung sounds with device cleared by the FDA for that purpose, analyze the lung sounds and provide indication on the presence of wheeze. The new algorithm's AI enabled modality for analysis of stethoscope recordings doesn't raise different questions of safety and effectiveness. Reference device was added to support that AI enabled algorithm designed for the

	Device	Predicate device	Reference device	Summary
	the point of care app and clinician app. The AI enabled algorithm runs automatically and returns a response for each audio file with the indication of wheezes to the telehealth server, which sends a response to both the clinician side and the patient side.	the point of care app and clinician app. The rule-based algorithm runs automatically and returns a response for each audio file with the indication of wheezes to the telehealth server, which sends a response to both the clinician side and the patient side.	returned to the front-end client where they are displayed to the user.	analysis of stethoscope recordings, was cleared previously by the FDA (K220766) Similar method of performance evaluation was employed for both devices.
Signal length	The length of the signal is dictated by the recording process of the compatible Stethoscope. The subject device processes the recordings in segments of up to 12 seconds while signals shorter than 6 seconds will not be processed.	The length of the signal is dictated by the recording process of the compatible Stethoscope. The subject device processes the recordings in segments of up to 12 seconds while signals shorter than 6 seconds will not be processed.	Was not specified.	Same as the predicate device
Data transfer and storage	The telehealth server sends the list of the recordings (identified by a unique identifier and time stamp) to the Tyto Insights for Wheeze	The telehealth server sends the list of the recordings (identified by a unique identifier and time stamp) to the TytoCare Lung Sounds	Server analyzes (algorithm) and stores (database) patient-related data and communicates with the other components of eMurmur. The interface to	Same as the predicate device, similar to the reference device.

	Device	Predicate device	Reference device	Summary
	Detection web server using its dedicated API. The server executes the Tyto Insights for Wheeze Detection which runs the algorithm and provides the results. Then the Tyto Insights for Wheeze Detection web server initiates the web user interface. All the software subsystems (server and storage) are hosted in the cloud and communicate through IP network.	Analyzer web server using its dedicated API. The server executes the TytoCare Lung Sounds Analyzer which runs the algorithm and provides the results. Then the TytoCare Lung Sounds Analyzer web server initiates the web user interface. All the software subsystems (server and storage) are hosted in the cloud and communicate through IP network.	the other components is a REST/JSON web API. The backend is not a part of eMurmur Heart AI (medical device); the backend is part of 'eMurmur', a non-medical device.	
Output	• Positive (wheeze suspected), • Negative (Wheeze not suspected), • The Tyto Insights for Wheeze Detection was not able to analyze the recording	• Positive (wheeze suspected), • Negative (Wheeze not suspected), The TytoCare lungs sounds analyzer was not able to analyze the recording	Identifies specific heart sounds that may be present, including S1, S2, physiological heart murmurs, pathological heart murmurs and the absence of a heart murmur.	Same as the predicate device Similarly to the reference device, the output is based on the AI algorithm's analysis.
Performance	The primary study endpoints and hypotheses were met for the intended patient population, the difference in AUCs was	The primary study endpoints and hypotheses were met for the intended patient population, the difference in AUC was in	Sensitivity: 85.0% (72.9%-92.5%) Specificity: 86.7% (74.9%-93.7%)	The study endpoints and hypotheses were met for the intended patient population. The performance of the Tyto Insights for Wheeze Detection

	Device	Predicate device	Reference device	Summary
	in favor of Tyto Insights for Wheeze Detection compared to the predicate device and in favor of the non-inferiority claim. Sensitivity and specificity were evaluated as the secondary endpoints. Estimate two-sided 95% CI): Sensitivity: 0.5465 [0.4304 – 0.6549] Specificity: 0.9895 [0.9684 – 0.9966]	favor of TytoCare Lungs Sounds Analyzer compared to the clinical readers. Sensitivity and specificity were evaluated as the secondary endpoints. Estimate two-sided 95% CI): Sensitivity: 0.69 [0.57-0.78] Specificity:0.92 [0.88-0.95]		is non inferior to the predicate device. The overall diagnostic performance show overall good diagnostic accuracy.
User interface for point of care and clinician apps	Web view	Web view	The user interface is not a part of eMurmur Heart AI (medical device); the user interface is part of 'eMurmur', a non-medical device.	Same as the predicate device

The Tyto Insights for Wheeze Detection like its predicate device the TytoCare Lung Sounds Analyzer (K221614) have the same intended use, in that both are intended to identify recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected in the same intended patient population (adult and pediatric 2 years and older) by the same user [Health Care Professional (HCP)] when self-administered by patient and/or the HCPs. Both devices are only intended to be interpreted by HCP and HCP advice is required for the patient to understand their result. Both are labeled OTC.

Both the Tyto Insights for Wheeze Detection and its predicate device are stand-alone software systems that deliver the same intended benefit (identify recordings where a specific abnormal lung sound suggestive of "Wheeze" is suspected). For both devices the source of the Lung sounds recordings is the compatible FDA cleared Tyto Stethoscope (K181612).
Similarly, to the predicate device, the Tyto Insights for Wheeze Detection system is composed of three sub-systems: Application Server (APS), Algorithm Server (ALS) and Web Server (WBS). The APS communicates with the ALS and implements an application programming interface API for communication with the telehealth server. The ALS receives an audio file as input and returns an analysis result of positive or negative regarding whether a wheeze was detected as output. The ALS sub-system is composed of an Algorithm and logic wrapper and Interface components. The code of the logic wrapper and Interface component of the ALS component is the same as of the ALS component of the predicate device, the Algorithm's component is different. The Algorithm of the proposed device is Artificial Intelligence enabled while the Algorithm of the predicate device is rule based. The AI Algorithm was trained with recordings acquired by the real-world use of the compatible Tyto Stethoscope. The differences in the software algorithm modality do not raise new questions of safety and effectiveness. A reference device (K220766) was added to provide an example of FDA cleared device that uses as an input recordings recorded by means of compatible digital stethoscope and analyzed by AI enabled algorithm. The different algorithm modality between the proposed device and the predicate device does require that the accuracy of the device be substantiated with valid performance data using acceptable methods. Similar approach of performance evaluation was employed for the reference device as well. The WBS provides a graphic indication whether a wheeze is detected in the recording. It can be utilized both in the patient and clinician side. The minor wording differences in the user interface did not raise

new questions of safety and effectiveness, the differences as compared to the predicate device did not introduce new critical tasks and didn't impact existing critical tasks.

Standards Conformance

- ANSI AAMI ISO 14971:2019, Medical devices - Application of risk management to medical devices
- ANSI AAMI IEC 62304:2006/A1:2016, Medical device software - Software life cycle processes
- ISO 15223-1 Fourth edition 2021-07, Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical device.

Performance evaluation:

The Tyto Insights for Wheeze Detection was subject to performance evaluation following methodology similar to the ones used to test the predicate device. A testing plan was developed and performed to verify that the Tyto Insights for Wheeze Detection meets its specifications. The main aspects of the testing plan included:

- SW verification and validation - The software including both custom developed software and OTS software, have been verified and validated and have been demonstrated to be safe and effective for its intended use. The software documentation level is basic per *Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff*, dated June 14, 2023. All required items related to software as required by FDA guidance for Basic Documentation Level have been included in this submission.
- Cybersecurity- all the applicable information to reflect effective cybersecurity management and to address the FDA's recommendations described in *Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act,* issue date March 2023, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*, issue date September 2023 and in the other FDA's applicable policies have been included in this submission.
- Performance evaluation - retrospective stand-alone performance evaluation of the "Tyto Insights for Wheeze Detection" device in detecting wheeze in the compatible Tyto Stethoscope lung recordings respective to ground truth and the predicate device.

- Human factors validation – the minor user interface modifications did not introduce new critical tasks and didn't impact existing critical tasks. Therefore, no additional human factors validation was required and the human factors testing for the predicate device was applicable.

The performance of the Tyto Insights for Wheeze Detection device in detecting wheeze in recordings acquired by the compatible Tyto Stethoscope has been evaluated on a retrospective validation dataset of Tyto Stethoscope recordings sourced from real world use of the FDA cleared compatible Tyto Stethoscope. 371 recordings (359 patients) corresponded to the intended patient population of the Tyto Insights for Wheeze Detection Software recorded (86 recordings were Wheeze positive and 285 negative). The sample included recordings with known pre-existing conditions (COPD or Asthma) (7.28%). The demographics of the validation dataset are presented here under in Table 2:

N=371 patients			
Age Group (Years)			
	Wheeze Positive	Wheeze Negative	Total
2-18	63 (24.2%)	197 (75.8%)	260 (70.08%)
>=18	23 (20.7%)	88 (79.5%)	111 (29.92%)
Gender			
	Positive	Negative	Total
Male	53 (27.3%)	141 (72.7%)	194 (52.29%)
Female	33(18.6%)	144 (81.4%)	177 (47.71%)

Table 2: Validation data-set demographics

To establish the ground truth, all of the recordings were read by three blinded experienced Pulmonologists at random, the binary ground truth was determined by majority vote of these three Pulmonologists.

For the characterization of the stand-alone accuracy, the automated binary result of the software has been compared to ground truth and specificity and sensitivity were calculated. This stand-alone accuracy is presented hereunder in Table 3:

Parameter	Estimate (two-sided 95% CI)
Sensitivity (Se)	0.54 (0.43–0.65)
Specificity (Sp)	0.98 (0.97–0.99)
Positive Predictive Value (PPV)	0.72 (0.48–0.89)
Negative Predictive Value (NPV)	0.97 (0.97–0.98)

Table 3: The stand-alone accuracy of the Tyto Insights for Wheeze Detection

To establish standalone accuracy and demonstrate substantial equivalency with the predicate device, the primary end point was area under the Curve (AUC) for the detection of wheezes by the proposed device compared to the TytoCare Lung Sounds Analyzer (K221614) for patients aged 2 years and above. The independent algorithm result was compared to the result of the TytoCare Lung Sounds Analyzer (K221614) for the same recordings to establish the non-inferiority of the automated algorithm respective to the predicate device. Success was defined as a lower bound of 95% two-sided CI for the difference in AUCs between the Tyto Insights for Wheeze Detection and the TytoCare Lung Sounds Analyzer (K221614) is higher than non-inferiority margin of -0.05 for the recordings. Non-inferiority of Tyto Insights for Wheeze Detection compared to TytoCare Lung Sounds Analyzer (K221614) is demonstrated in Table 4:

	AUC	LCI	UCI
TytoCare Lung Sounds Analyzer (K221614) [Analyzer]	0.9085	0.8678	0.9372
Tyto Insights for Wheeze Detection [Insights]	0.9654	0.9459	0.9790
Insights - Analyzer	0.0570	0.0289	0.0917

Table 4: Primary Endpoint stand-alone assessment: Tyto Insights for Wheeze Detection compared to TytoCare Lung Sounds Analyzer (K221614)

AUC – Area Under the receiver operating characteristic Curve; LCI/UCI – lower/upper bound of two-sided 95% bootstrap (BCa) Confidence Interval

Non–inferiority of Tyto Insights for Wheeze Detection compared to TytoCare Lung Sounds Analyzer (K221614) for 2 years and above was established. Similar effect trend was also shown within the subgroup analysis, as evidence that the device accuracy is consistent with age groups and relevant pre-existing conditions.

Conclusion

The Tyto Insights for Wheeze Detection Software has the same intended use and indication for use as the predicate. The Tyto Insights for Wheeze Detection is only compatible with the FDA cleared TytoCare Stethoscope that provides the input stethoscope recordings. The minor differences in the user interface wording and software algorithm modality do not raise new questions of safety and effectiveness. Non–inferiority of Tyto Insights for Wheeze Detection compared to the predicate device for intended patient population was established. Thus, we conclude that the Tyto Insights for Wheeze Detection is as safe and effective as the predicate device.